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Australian Standard 2394—1980

CONDITIONING EQUIPMENT FOR THE TREATMENT OF NOCTURNAL ENURESIS (BEDWETTING ALARMS)

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THE FOLLOWING SCIENTIFIC, INDUSTRIAL, CONSUMER AND GOVERNMENTAL organizations and departments were officially represented on the committee entrusted with the preparation of this standard:

Australian Consumers Association

Australian Federation for Medical and Biological Engineering

Confederation of Australian Industry

Health Commission of New South Wales

Health Commission of Victoria

Hospitals Department, South Australia

Medical Department, W.A.

National Health and Medical Research Council

Royal Alexandra Hospital for Children

Royal Children's Hospital, Melbourne

University of New South Wales

Also represented on the committee was Committee EL/18, Electromedical Equipment.

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AUSTRALIAN STANDARD

CONDITIONING EQUIPMENT FOR THE TREATMENT OF NOCTURNAL ENURESIS (BEDWETTING ALARMS)

AS 2394—1980

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PREFACE

This standard was prepared by the Association's Committee on Enuresis Alarms at the request of the National Health and Medical Research Council, which felt that although the use of enuresis alarms in the conditioning treatment of nocturnal enuresis (bedwetting) was proven and effective, the range of conditioning equipment varied in quality and some types were considered to be potentially dangerous in that under certain adverse conditions they could cause skin ulceration due to electrolysis of urine or perspiration in contact with the skin.

The items covered by this standard are considered to be electromedical equipment, as described by AS 3200, Approval and Test Specification for Electromedical Equipment—General Requirements, and the relevant requirements of that standard will be applicable to these items. However, since the majority of enuresis alarms are battery powered and not intended for connection to the mains, it was not appropriate that the specific safety requirements applying to them (beyond those set out in AS 3200) should be the subject of a separate approval and test specification, and accordingly this standard deals with both performance and safety matters. The committee responsible for this standard was formed under the auspices of the Association's Consumer Standards Advisory Committee, in recognition of the fact that unlike most electromedical equipment, enuresis alarms are available to the public through a variety of outlets other than the normal suppliers of electromedical equipment. During preparation of this standard direct liaison was maintained with the Committee on Electromedical Equipment.

It should be noted that Clauses 3(c), 4.3 and 4.5 are not intended to preclude the development of conditioning equipment which would automatically reset after a certain period, returning to a condition in which the next passage of urine would be sensed even though the previous urine may still be present on the detector. Should such equipment be developed, consideration would be given to revision of the standard.

This standard may require reference to the following standards:

AS 1259	Sound Level Meters Part 2—Type 2, Precision
AS 3200	Approval and Test Specification for Electromedical Equipment—General Requirements
AS C100	Approval and Test Specification for Definitions and General Requirements for Electrical Materials and Equipment
AS C112	Approval and Test Specification for Plugs and Plug Sockets

CONTENTS

STANDARDS ASSOCIATION OF AUSTRALIA

Australian Standard
for
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FOREWORD

The condition of nocturnal enuresis is quite common among children between the ages of 5 and 15 years, with over 100 000 children being currently affected in Australia. The majority of children affected are in the younger age group, but the condition may persist into adult life. In spite of extensive research the precise cause is not known, although it is clear that major organic disease or psychopathology is rarely the cause.

The use of conditioning equipment in treating nocturnal enuresis has been demonstrated to be successful in approximately 80 percent of children treated, and although some patients may relapse, a further course of treatment may lead to a permanent cure in about half of these cases. Treatment for nocturnal enuresis is not normally undertaken with children under the age of about 5 years, and successful treatment using conditioning equipment requires the active cooperation of both parent and child. It should be borne in mind that conditioning treatment, although widely used and effective, is not the only form of treatment of this condition. Certain situations may indicate the need for further investigation and possibly a different form of treatment or referral to a specialist. Furthermore, conditioning treatment is only one aspect of total medical management of enuresis, and should be carried out under competent professional supervision, preferably that of the family doctor or a registered clinical psychologist.

It is worth noting that although the stimulus provided by the conditioning equipment, in the form of an audible signal or a light, may be considered to be aversive to the extent that it awakens the subject from sleep, the use of painful or clearly aversive stimuli such as electric shock is strongly condemned and is precluded in this standard under Clause 3(*h*).

It is essential that regardless of the source from which the equipment is obtained, it should be accompanied by proper instructions. For this reason the standard includes requirements regarding the subjects covered by instructions provided with enuresis alarms, with the objective that proper written instructions will be available to users.

SPECIFICATION

1 SCOPE. This standard specifies requirements for the performance and safety of equipment for use in the conditioning treatment of nocturnal enuresis (bedwetting). Such items of equipment are commonly referred to as enuresis alarms. The standard applies to both battery-powered equipment and mains-powered equipment.

2 DEFINITIONS. For the purpose of this standard, the following definitions apply:

Nocturnal enuresis—the involuntary passage of urine during sleep, beyond the age at which continence is usually achieved.

Detector—a device designed to be situated close to the urinary orifice which will indicate the presence of urine either by a change of electrical impedance or by generation of an electric potential with the device.

NOTE: Such devices commonly take the form of a mat placed in the bed or a pad worn near the urinary orifice.

Control unit—an apparatus which, in response to an indication by the detector, will provide a signal intended to condition the patient to maintain urinary continence.

Conditioning equipment (also known as 'enuresis alarms')—the combination of the detector and the control unit and any interconnecting wiring.

3 ELECTRICAL SAFETY REQUIREMENTS. Conditioning equipment shall comply with the following requirements:

(a) The maximum patient-circuit current shall not exceed 100 μA under any circumstances of operation. This shall include current that flows when the detector acts as a primary cell.

(b) The equipment shall not be capable of generating potential differences in excess of 20 V peak. This requirement includes transient voltages which may be produced by inductive components.

(c) Provision shall be made so that, when the control unit is activated by the detector, the detector shall be automatically isolated from the power source, to that extent that no more than 10 μA may flow in the detector circuit, and the detector shall remain isolated until manually reset prior to further use.

(d) Exposed metal parts of the control unit shall be electrically insulated from the detector circuit.

(e) Any wires from the control unit to the detector shall be attached to the detector in such a way that, when the attachment of the wires to the detector is tested in accordance with Appendix A, the wires will not break away from the detector or become disconnected from the detector. Connections to the detector shall be suitably insulated to prevent patient contact.

NOTE: The wires from the control unit should preferably be attached permanently to the detector to avoid the risk of accidental disconnection, or increased resistance through corrosion of the connectors.

(f) Battery-operated equipment shall not incorporate any connector which is capable of being accommodated in a plug socket or plug of the type described in Fig. 1(a) of AS C112.

(g) Connections to the control unit which are intended for different purposes, e.g. connections to the detector and connections to additional signal units, shall not be interchangeable.

(h) The conditioning signal provided by the control unit shall not take the form of an electric current applied to the patient.

(j) Equipment which includes provision for recharging batteries using a battery charger shall be such that, while the batteries are being charged, the equipment shall not be operable and the batteries shall be completely disconnected from the equipment.

(k) Mains-powered conditioning equipment shall, in addition to complying with the foregoing requirements (a) to (j), comply with the relevant requirements set out in AS 3200 for Class II equipment and Class B patient-circuits.

NOTE: Recommendations regarding general safety matters are set out in Appendix D with the object of providing for increased safety in the use of conditioning equipment.

4 PERFORMANCE.

4.1 Sensitivity. The equipment should be designed so that its sensitivity is such that—

(a) the incidence of failure of the equipment to correctly respond to small volumes of urine is minimized; and

(b) the incidence of false activations of the equipment in response to perspiration is minimized.

NOTE: Compliance with the requirements of Clause 4.2 will provide a reasonable assurance that the objective of (a) above will be met. The question of a test to assess compliance with (b) above, having general application to a wide range of detector types, is under continuing consideration. For the present, however, it is not considered practical to include such a test.

4.2 Activation Time. The conditioning signal shall be activated as soon as possible after the onset of a flow of urine on to the detector. When the equipment is tested in accordance with Appendix C, the activation time for a signal to be given following complete application of the test solution to the detector shall be not more than 5 s for any test.

4.3 Conditioning Signal. The signal, once activated, shall continue to operate until manually re-set, i.e. the signal will 'latch in'.

4.4 Auditory Signals. Conditioning equipment which provides an auditory signal shall be capable of producing a sound level of not less than 85 dB(A) when measured with a sound level meter complying with AS 1259, Part 2, at a horizontal distance of 1 m from the sound source with the control unit in its normal orientation for use.

4.5 Connecting Lead. The lead from the detector to the control unit shall be of sufficient length to allow the control unit to be placed far enough from the bed to require that the patient must leave the bed to reset the unit.

4.6 Reversible Polarity Plug(s). It is recommended that equipment incorporating re-usable detectors should be provided with a reversible polarity plug or plugs for connection of the lead from the detector to the control unit, in order to provide for random changes of polarity in connecting the detector, thus minimizing the effect of electrolysis on the detector.